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The effect of ligasure use on serum parathormone and calcium levels in thyroidectomy surgery

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ABSTRACT

Aims: The use of the modern bipolar closure system enabling a more rapid dissection and hemostasis has increased in thyroidectomy. A significant complication encountered following thyroidectomy is hypocalcemia. This study evaluated the effect of LigaSure™ (LS) use only on postoperative parathormone and calcium levels during total thyroidectomy.

Methods: Patients who underwent total thyroidectomy between June 2018 and January 2022 participated in the research. The patients on whom LS was used without any ligature during thyroidectomy were categorized as group 1; those on whom the ligature was used were categorized as group 2. Both groups were compared in terms of demographic features, postoperative hypocalcemia, and other complications.

Results: In total, 84 patients meeting the criteria were included in the study. Group 1 consisted of 36 patients and group 2 of 48 patients. The postoperative 1st-day hypocalcemia rate was observed to be higher in the LS group (47.2% for group 1 and 22.9% for group 2; p=0.019). However, on the postoperative 30th day, both groups were observed to be evened out in terms of hypocalcemia, and the difference between the two groups lost its statistical significance (2.8% for group 1 and 2.1% for group 2; p=0.836). On the postoperative 30th day, no statistically significant differences were observed in either group in terms of hypoparathyroidism, permanent hypocalcemia, and other complications.

Conclusion: Although the use of LS increases temporary hypocalcemia in total thyroidectomy, it does not increase the risk of permanent hypocalcemia.

Keywords: Ligasure, thyroidectomy, serum parathormone, calcium levels, surgical impact

INTRODUCTION

Total thyroidectomy is one of the most commonly used treatment options in surgical practice. Postoperative hypocalcemia (PH), a surgery-related complication encountered in patients, can lead to serious symptoms and an increase in hospitalization duration. In cases where PH is permanent, using calcium and Vitamin D supplements for long periods can increase medical expenditure and adversely affect the patient's life quality.[1] Although there is no definite consensus on the definition of hypocalcemia, it can be identified as a total serum calcium level lower than 8.5 m/g.[1] PH is defined as temporary when it goes away after six months and permanent if it continues after six months. Postoperative temporary hypocalcemia incidents in the literature vary but are listed as being between 0.3% and 49%; for permanent hypocalcemia, the incident rate is between 0% and 13%.[1] The most common reason for PH is parathyroid gland (PG) ischemia.[2] Therefore, it is of the utmost importance to maintain PG health to decrease PH levels.[3,4]

The use of modern bipolar closure systems, enabling a more rapid dissection and hemostasis has increased in thyroidectomy, like in many other fields. These devices are shown to have positive effects on the duration of surgery, blood loss, analgesic need, incision cosmetic, and hospitalization period.[5] However, the advantages and disadvantages of these devices on the protection of PG functions during thyroidectomy are still unclear. In addition to the limited research on this topic in the literature, several studies have proposed contradictory conclusions.[6,7] The present study aims to compare the PH levels of patients to whom conventional ligature was applied and the PH levels of those to whom only LigaSure™ (LS) was applied without ligature for bleeding control during total thyroidectomy.

METHODS

This study was conducted with the approval of the Hatay Mustafa Kemal University Non-interventional Clinical Researches Ethics Committee (Date: 23.12.2021, Decision No: 05). All patients provided informed consent in accordance with the institutional review board guidelines and in compliance with the Declaration of Helsinki. The research was retrospectively carried out in the General Surgery Clinic of Ankara Etlik City Hospital by examining the files and data

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of patients in the hospital's electronic database on whom total thyroidectomy was performed by the same surgical team between June 2018 and January 2021. Patients who had a previous thyroidectomy, those whose thyroidectomy was not totally performed, and those who underwent cervical lymphoma nodule dissection at the same time were excluded from the research. Additionally, patients with a calcium metabolism disorder before surgery, those who required intramuscular stitching due to excision of intraoperative parathyroid tissue, and those whose parathyroid tissue was identified during the pathological examination were also excluded. Furthermore, patients with incomplete data, those we could not contact, and those under the age of 18 were not included in the study. Patients who met the research criteria were included in the research after the collection of their informed consent forms. The patients on whom LS was used without any ligature during thyroidectomy were categorized as group 1; those on whom the conventional ligature was used were categorized as group 2. In group 1, an LS small jaw instrument and Valleylab™ LS10 generator (Valleylab, Boulder, CO, USA) were used, and 3/0 polyglactin was used for the ligation process in group 2. A Hemovac drain was placed in every patient. On the postoperative 1st day, the calcium levels were checked, and on the 30th day, both the calcium and parathormone values were examined. Patients whose blood calcium values were under 8.5 mg/dl (2 mmol/L) were accepted as hypocalcemic. Intravenous calcium was applied to patients who had clinically hypocalcemic symptoms. In addition, the patients whose hypocalcemia continued on the postoperative 30th day were contacted after six months, and they were asked whether or not they still needed calcium replacement. Statistical analysis was conducted after examining the demographic information, radiological results, the diameter of the biggest nodule, retrosternal extension, tracheal pressure, surgery indications, findings of the fine-needle aspiration biopsy, pathological results, postoperative blood calcium levels, parathormone levels, and all related complications (bleeding, laryngeal nerve injury, permanent hypocalcemia) of the patients.

Statistical Analysis

Constant variables were expressed as mean±standard deviation and median (min-max); categorical data were expressed with numbers and percentages. An independent T test was applied for the analysis of the constant variables between the two groups that complied with normal distribution; the Mann-Whitney U test was used for those that did not comply. Pre-post comparisons within the groups were carried out with the Wilcoxon signed-ranks test. In the comparisons between the discrete/categorical data, the Chi-square test (Fisher's exact test) was applied. The analyses were made with IBM's SPSS Package Program version 26.0 (IBM Corporation, Armonk, NY, USA). The statistical significance level was deemed as $p<0.05$.

RESULTS

The total number of patients who underwent thyroidectomy was 116. Eighty-four patients who met the research criteria were included in the study. Group 1 consisted of 36 patients, 32 of whom were female and 4 male. The mean age for group 1 was 45.5±13.3. Group 2 consisted of 48 patients, 42 of whom were female and 6 male. The mean average for this group was 41.2±11.1. While there were no significant differences between the groups in terms of age, sex, hospitalization duration, indication, and pathology, the monitoring period and the diameter of the maximum nodule being ≥4cm were significantly statistically identified as higher in group 1 ($p<0.001$). In the results of the FNAB carried out after surgery, malignity and the significance of undetermined atypia were significantly determined as higher ($p<0.001$) (Table 1).

Table 1. Comparison of the groups according to their sociodemographic characteristics and clinical parameters

	LigaSure™ (n=36)	LIGATURE (n=48)	p
Age (year) (mean±SD)	45.5±13.3	41.2±11.1	0.113*
Hospitalization period (days) [median (min-max)]	2 (1-5)	2 (2-3)	0.670**
Monitoring period (days) [median (min-max)]	1192.5 (68-1610)	528 (50-990)	<0.001**
Gender, n (%)			
Female	32 (88.9)	42 (87.5)	0.846***
Male	4 (11.1)	6 (12.5)	
Pathology (post-op) , n (%)			
Nodular hyperplasia	23 (63.9)	36 (75.0)	0.629***
Papillary carcinoma	10 (27.8)	9 (18.8)	
Follicular adenoma	2 (5.6)	1 (2.1)	
Follicular carcinoma	1 (2.8)	1 (2.1)	
Graves	0 (0.0)	1 (2.1)	
Maximum nodule diameter (cm), n (%)			
<4 cm	12 (33.3)	39 (81.3)	<0.001***
≥4 cm	24 (66.7)	9 (18.8)	
Retrosternal goiter, n (%)			
Yes	5 (13.9)	7 (14.6)	0.928***
No	31 (86.1)	41 (85.4)	
Ultrasound, n (%)			
Multinodular	36 (100.0)	45 (93.8)	0.256***
Solitary nodule	0 (0.0)	3 (6.3)	
Computed tomography, n (%)			
No	28 (77.8)	42 (87.5)	0.197***
Retrosternal goiter	3 (8.3)	5 (10.4)	
Trachea pressure	3 (8.3)	1 (2.1)	
Magnetic resonance, n (%)			
No	35 (97.2)	48 (100.0)	0.429***
Trachea pressure	1 (2.8)	0 (0.0)	
Scintigraphy, n (%)			
Yes	0 (0.0)	2 (4.2)	0.504***[a]
No	36 (100.0)	46 (95.8)	
Fine-needle aspiration biopsy, n (%)			
Benign	22 (61.1)	27 (56.3)	<0.001***
Malign	0 (0.0)	5 (10.4)	
Significance undetermined atypia	0 (0.0)	16 (33.3)	
Non-diagnostic	3 (8.3)	0 (0.0)	
Malignant suspect	1 (2.8)	0 (0.0)	
Without biopsy	10 (27.8)	0 (0.0)	

*Independent samples T test, **Mann–Whitney U test, ***Chi-square test ([a]Fisher's exact test), SD: Standard deviation, min: Minimum, Max: Maximum

The hypocalcemia encounter rate on the postoperative 1st day was observed to be statistically significantly higher in group

1 (47.2% in group 1 and 22.9% in group 2; p=0.019). On the postoperative 30th day, however, the hypocalcemia in both groups was observed to have evened out, and the difference between the groups lost its statistical significance (2.8% and 2.1%, respectively; p=0.836). When both groups were internally compared from the postoperative 1st day until the 30th day in terms of the difference in hypocalcemia rates, the hypocalcemia rates in both groups were determined to have significantly decreased (p<0.001 and p=0.002, respectively) (Table 2). It was determined that there were no statistically significant differences between the two groups in terms of hyperparathyroidism on the postoperative 30th day, permanent hypocalcemia after 6 months, and other complications (Table 3).

Table 2. Comparison of hypocalcemia rates

	LigaSure™ (n=36)	LIGATURE (n=48)	p
1st day of hypocalcemia			
No	19 (52.8%)	37 (77.1%)	0.019*
Yes	17 (47.2%)	11 (22.9%)	
30th day of hypocalcemia			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Total	36 (100%)	48 (100%)	
	p<0.001**	p=0.002**	

*Chi-square test, **McNemar's test

Table 3. Complications and comparison of hypoparathyroidism and permanent hypocalcemia rates on the post-operative 30th day

	LigaSure™ (n=36)	LIGATURE (n=48)	p
30th day of hypoparathyroidism			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Complications (except for temporary PH)			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Permanent hypocalcemia			
No	35 (97.2%)	47 (97.9%)	0.836*
Yes	1 (2.8%)	1 (2.1%)	
Total	36 (100%)	48 (100%)	

*Chi-square test, PH: Postoperative hypocalcemia

DISCUSSION

The most common cause of hypocalcaemia after thyroidectomy is hypoparathyroidism.[3,4] The fact that the PGs are situated in a localization close to the thyroid capsule and recurrent laryngeal nerve and sometimes localized in the thyroid gland leads to an increase in PG damage.[8] Often, as the blood circulation of the PG is disrupted, hypoparathyroidism can develop, and this happens due to ischemia, direct injury, or the excision of the PG.[9] The PGs of the patients who participated in our research were regularly intraoperatively checked in terms of their sensitive anatomy and vitality. Cases where the researchers were sure that only the four PGs were intact and those that did not have a PG in the pathology results were included in the research; thus, factors that might have inadvertently affected the research results were avoided.

Although the use of modern bipolar closure tools such as LS has made a positive impact on surgery duration and hemostasis, injuries related to lateral thermal expansion still pose a risk. Opinions about the safest distance required to avoid thermal injury differ between 1-3 mm.[10-13] Studies comparing the use of LS (LigaSure™) and ligature in terms of pH levels and postoperative hypoparathyroidism have yielded various, often differing, results.[7,14-16] We believe that the difference in the results may arise from the extent of the thyroidectomy (total, subtotal, with neck dissection), whether the postoperative calcium aid was applied regularly or not, or because the surgeries in these particular studies were carried out by different surgeons.[17-22] As the surgical experience increases, so does the identification of PG and recurrent laryngeal nerves, and, as a result, complications are expected to decrease.[23,24] Therefore, the fact that the same surgeons performed the operations and the presence of patients that were only going through total thyroidectomy are key factors in the current research. No calcium replacement was applied to the patients with PH as long as they did not have clinical symptoms. This way, our research was kept homogenous in terms of clinical methods, and, therefore, we attained more objective results.

Some studies indicate that PH levels might be lower due to the side thermal effect of LS.[15,17] Nonetheless, Petrakis et al.[7] stated that the use of LS reduces the PH damage. It was seen in our research that on the 1st postoperative day, while the hypocalcemia rate in the LS group was statistically higher, on the 30th day, hypocalcemia and hypoparathyroidism rates statistically significantly evened out in both groups; furthermore, the significance of the statistical difference between the groups disappeared. We also think that the high frequency of PH in the LS group on the 1st day might be related to the necessity of opening a bigger pocket in the tissue to place the LS mouth, which, relatively, has a broader distance compared to the clamp; also, it might be related to side heat expansion. In addition, considering the frequent encounter of the presence of a ≥4 cm thyroid nodule in the LS group, we believe that a possible surgical dissection difficulty might lead to this. The statistical similarity between the hypocalcemia and hypoparathyroidism rates and permanent hypocalcemia on the postoperative 30th day leads us to think that LS creates an impact on PG on a level that cannot distract the revascularization process; therefore, the level of PH on the 1st day is acceptable. Despite this, we believe that in thyroidectomy with LS, the use of ligature instead of LS in PG localization might eliminate the issue.

Although it was stated in several studies in which the ligature and LS are compared that recurrent laryngeal nerve injury is seen less in LS, other reports indicate that the injury risk is similar.[7,14,25-27] However, in this study, we did not encounter any recurrent laryngeal nerve injury or aphonia. Although this leads us to think that there might be no changes in recurrent laryngeal nerve injury risk in LS, we believe the results might differ in research that is conducted with larger numbers of patients.

Limitations

Our study has a few limitations. The retrospective design and the limited number of cases are prominent among them.

Nevertheless, we believe that analyzing surgeries performed by a single surgeon within the same timeframe provides reliable results for comparing ligature and LS.

CONCLUSION

Compared to a ligature, LS use in total thyroidectomy leads to higher rates of permanent hypocalcemia. However, it does not increase the risk of permanent hypocalcemia. Using ligature in PG localization in thyroidectomy with LS can eliminate this issue.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the Hatay Mustafa Kemal University Non-interventional Clinical Researches Ethics Committee (Date: 23.12.2021, Decision No: 05).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

Declarations

This manuscript was prepared without the use of artificial intelligence or assisted technologies in the production of text and figures. The authors are fully responsible for the content and originality of the manuscript, and confirm the absence of plagiarism.

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